



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,357	09/08/2003	Fraser Harvie	00167-375002	9556

23715 7590 06/29/2005

JOEL R. PETROW
SMITH & NEPHEW, INC.
1450 BROOKS ROAD
MEMPHIS, TN 38116

EXAMINER

LEWIS, RALPH A

ART UNIT	PAPER NUMBER
----------	--------------

3732

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,357

Applicant(s)

HARVIE ET AL.

Examiner

Ralph A. Lewis

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-94 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-94 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09082003</u> . | 6) <input type="checkbox"/> Other: ____. |

Statutory Double Patenting Rejection

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 28, 29, 39, 30-38, 88 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 and 58, respectively, of prior U.S. Patent No. 6,620,185. This is a double patenting rejection.

Obvious-type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 3732

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27, 40-87 and 89-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-91 of U.S. Patent No. 6,620,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because

Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 62, critical relationships between the recited elements necessary for operation of the device are not clearly set forth. More particularly it is unclear how the "piercing element " is related to the claimed "lumen."

In claim 63, it is unclear what objectively ascertainable limitations applicant is trying to impose on the claimed "surgical instrument" with limitations directed to "the fixation device" which is not part of the "surgical instrument" being claimed (i.e. "for delivery of . . . a fixation device").

In claim 64, it is unclear how the "suture feed mechanism" relates to the "fixation instrument." Moreover, insufficient structure is claimed for this element in order for it to perform its claimed function of delivering a suture.

In claim 66, it is unclear how the "heating element" is related to the "fixation device." The recited elements of a device must be reasonably related so as to present an operable device capable of performing the functions claimed.

In claim 68, it is unclear how the movable needle relates to the previously claimed structure.

In claim 69, insufficient structure is claimed for the "probe" for it to accomplish the claimed function.

In claim 76, it is unclear how the mixing device relates to the previously claimed elements.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, 10, 11 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Chervitz et al (5,665,110).

Art Unit: 3732

Chervitz et al disclose a method wherein an opening (14, 15, 16) is formed in bone 10, a fixation device (suture 17, 18, 19) is positioned in the opening, a flowable adhesive material (24) is delivered to the opening and then cured (changing the state) to secure the fixation device in the opening.

Claims 1, 3-6, 9, 10, 20, 22, 23, 62-65, 69-72, 74-77, 79, 81 -85, 92 and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Hannam et al (5,649,959).

Hannam et al disclose a method wherein an opening is formed in two connecting tissues (artery 24 and surrounding tissue including skin) a fixation device 30, 36 is positioned therein and secured with flowable gelatinous material 51 inserted into the opening and cured.

In regard to apparatus claim 62, note handpiece 26, piercing element (column 6, line 47), lumen 32. Note further suture feed mechanism 38, probe 38, reservoir 33 and mixing device 33. The broad manner in which the apparatus is claimed leaves it open to any number of interpretations.

Claims 1, 2, 4-6 and 19- 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Halpern (US 4,532,661).

In Figure 10 note opening 24 with fixation device 32 secured therein with cement which includes bone fragments (note column 10, lines 15-20).

Art Unit: 3732

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 8, 19, 20, 86, 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al (5,665,110) in view of Gerhart (4,843,112). Chervitz et al disclose a method wherein an opening (14, 15, 16) is formed in bone 10, a fixation device (suture 17, 18, 19) is positioned in the opening, a flowable adhesive material (24) is delivered to opening and then cured (changing the state) to secure the fixation device in the opening. The Chervitz et al adhesive material may be "any adhesive material as is suitable for implantation in the human body" including "adhesives" and "bone paste" (column 4, lines 29-37). Gerhart et al disclose an improved bone cement for use in "bone/implant fixation" that is comprised of a polymer into which bone fragments which have been removed from the patient have been mixed (note column 7, lines 50-54) in order to enhance osteoinduction or new bone formation into the cement. To have selected the improved Gerhart polymer adhesive with bone chips for enhanced osteoinduction as the adhesive called for by Chervitz et al would have been obvious to one of ordinary skill in the art.

Claims 12-16, 18, 26, 40-51, 54-61 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al (5,665,110) in view of Bartlett (5,441,502).

Chervitz et al disclose a method wherein an opening (14, 15, 16) is formed in a bone 10, a fixation device (suture 17, 18, 19) is positioned in the opening, a flowable adhesive material (24) is delivered to the opening and then cured (changing the state) to secure the fixation device in the opening. The suture is then used to anchor soft tissue (e.g. a ligament) to the bone. Chervitz et al do not disclose the piercing of the soft tissue prior to the setting of the fixation device in the bone as is required by claims 12 and 40. Bartlett, however, teaches that for fixing soft tissues to bone with a fixation device that it is desirable to first position the soft tissue on the bone in the desired location where it is then pierced and a hole formed in the bone in order to improve the precision of attaching the soft tissue to the optimum location. To have used the Bartlett method for positioning the Chervitz et al fixation device in the proper location would have been obvious to one of ordinary skill in the art in order to optimize the locating soft tissue with respect to the bone.

Claims 17, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al (5,665,110) in view of Bartlett (5,441,502) as applied to claim 12 above, and further in view of Gerhart et al (4,843,112).

Chervitz et al disclose that adhesive material 24 may be "any adhesive material as is suitable for implantation in the human body" including "adhesives" and "bone paste" (column 4, lines 29-37). Gerhart et al disclose an improved bone cement for use in "bone/implant fixation" that is comprised of a polymer into which bone fragments which have been removed from the patient have been mixed (note column 7, lines 50-

54) in order to enhance osteoinduction or new bone formation into the cement. To have selected the improved Gerhart et al polymer adhesive with bone chips for enhanced osteoinduction as the adhesive called for by Chervitz et al would have been obvious to one of ordinary skill in the art.

Claims 24 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al (5,665,110).

Chervitz et al do not explicitly set forth any particular sizes or method of implantation, however, one of ordinary skill in the art would have found obvious the particular size claimed and the endoscopic delivery conventional.

Claims 86 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirza (5,928,239) in view of Gerhart et al (4,843,112).

Mirza discloses a method wherein an opening is formed in the bone of a patient and then the opening filled with bone cement arthroscopically in order to increase the strength of the bone. Mirza does not disclose the use of bone polymer blend for the cement as required by claim 86. Gerhart et al, however, disclose the prior art use of mixing bone material recovered from patient (column 7, lines 50-55) in a polymeric cement. The Gerhart et al cement exhibits "good biomechanical strength" and the use of bone particles permits the eventual replacement of the cement with developing bone tissue. To have selected the Gerhart et al good strength bone cement that permits

Art Unit: 3732

bone growth for the bone cement used in the Mirza method would have been obvious to one of ordinary skill in the art in view of the teachings by Gerhart et al.

Claims 89-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti et al (5,735,875).

In regard to claims 89-91, Bonutti et al disclose in Figures 11A-11C a method wherein an opening is formed between two body tissues 186, 188, a hollow sleeve member 190 is positioned therein such that its ends extend beyond both ends of the opening. The extending ends 192, 198 are then deformed to secure the two bodies 186 and 188 together. Bonutti et al does not explicitly state that the two body members 186 and 188 may be soft body tissues, however, one of ordinary skill in the art would have recognized such a use as being obvious. Additionally, Bonutti et al fail to explicitly disclose the material of sleeve 190, one of ordinary skill in the art, however, would have found the selection of a thermoplastic as suggested in the other examples of Bonutti et al where members are deformed obvious.

In regard to claims 92 and 93, In Figure 2 Bonutti et al disclose a method wherein two members 160 and 168 are secured together by forming an opening therethrough. Screw member 162 is positioned therethrough and plug members 166 170 are attached at opposite ends and heated and softened "to flow about the joint" (column 4, line 21). Bonutti et al indicates that member 168 is a plate rather than issue as required by claim 92. Merely using the method for securing two tissues together rather than a tissue and a plate would have been obvious to one of ordinary skill in the art.

Prior Art


Applicant's information disclosure statements of December 18, 2000 and August 13, 2001 have been considered and an initialed copy enclosed herewith.

Kurland (4,585,458), Ray et al (5,665,111), Tahl (5,683,419), Jacob et al (5,893,856), Bonutti (5,935,131), Grafton et al (5,964,783), and Lax (5,976,127) are made of record.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (703) 872-9306. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (571) 272-4720.

R. Lewis
June 24, 2005


Ralph A. Lewis
Primary Examiner
AU3732